Instruction and Technical Manual

evo Recorder and Docking Station

evo Recorder firmware version 2.xx
evo Docking Station firmware version 1.xx

SPACELABS Healthcare

50-0037 Rev B

Contents Page

1. INTRODUCTION 5

1.1 About this Manual 5
1.2 Disclaimer 5

2. SAFETY AND REGULATORY 7

2.1 Device Description 7
2.2 Indications and Intended Use 9
2.3 Contraindications 10
2.4 Precautions 10
2.5 Warning 10
2.6 Adverse Reactions 10
2.7 Caution 10
2.8 Conformance to Standards 11
2.9 Adjustment, Replacement of Parts, Maintenance & Repair 11
2.10 Defects and Abnormal Stresses 11
2.11 Modifications 12
2.12 Declaration of Conformity 12
2.13 Explanation of Markings 12
2.14 Manufacturer 13

3. DETAILED OPERATING INSTRUCTIONS 15

3.1 First-time Use 15
3.2 Minimum Software Versions 15
3.3 Manual Recording Identification 15
3.4 Recording Procedure Overview 16
3.5 Prepare the Recorder 16
3.6 Prepare the Patient 18
3.7 Apply the Electrodes 19
3.8 Hook up the Recorder 20
3.9 Check the ECG Quality 22
3.10 Instruct the Patient 23
3.11 On the Patient's Return 24
3.12 Download the Recording 25
3.13 Analyse the Recording 26

4. MAINTENANCE 27

4.1 Cleaning and Disinfecting the evo Recorder 27
4.2 Dynamic Energy Source Replacement Kit 28
4.3 evo Recorder Accessories and Consumables 29

5. TECHNICAL MANUAL 31

5.1 evo Recorder Technical Specifications 31
5.2 evo Docking Station Technical Specifications 33
5.3 evo Error Messages 34
5.4 Software Error Messages and Warnings 34
5.5 Firmware Update Utility 34
5.6 Installation of the Docking Station 34
5.7 Infrared Data Transfer 35
5.8 User Labelling of the Recorder 35
5.9 User labelling of the docking station 36

6. INDEX 37

Copyright 2008 Spacelabs Healthcare Ltd.
1 Harforde Court, John Tate Road, Hertford SG13 7NW

1. INTRODUCTION

1.1 About this Manual

This manual contains detailed operating instructions for the evo Holter ECG recorder and the evo docking station. It is one of 3 manuals for this recorder.

- evo Recorder Instruction and Technical Manual
- evo Recorder Quick Guide – Sentinel Users
- evo Recorder Quick Guide – CardioNavigator Plus

This manual has 6 chapters:

Chapter 1	Introduction
Chapter 2	Safety and Regulatory
Chapter 3	Detailed Operating Instructions
Chapter 4	Maintenance
Chapter 5	Technical Manual
Chapter 6	Index

1.2 Disclaimer

Every effort has been taken to ensure the accuracy of this manual but Spacelabs Healthcare cannot take liability for consequences caused by errors or omissions. You are advised to check with Spacelabs Healthcare on any point on which you are unsure or need confirmation.

This page is intentionally blank.

2. SAFETY AND REGULATORY

2.1 Device Description

The evo recorder is a compact, lightweight three channel Holter Ambulatory ECG recorder utilizing a digital storage technique to store the ECG recording onto an internal flash memory.

This recorder provides continuous monitoring of 3 leads of ECG for 24 hours or 48 hours.

The on board display allows the user to monitor the ECG and pacing detection during hook-up. Pacing detection is always enabled on all 3 channels. It is important to verify the ECG quality before starting the recording.

Menu navigation is controlled by the single button on the front of the recorder. This button also acts as a Patient Event button when Recording Mode is active. This enables the patient to indicate symptomatic episodes in the recording for correlation with the Patient Diary.

Four separate lead wires with color coded snap leads are used to connect the electrodes on the chest to the recorder.

The internal Dynamic Energy Source is automatically re-energized when each recording is downloaded into the Holter Analyser via the docking station.

Recordings may be analyzed using an Impresario Holter analyzer in conjunction with the Sentinel Cardiology Information Management software.

The recorder is also compatible with the CardioNavigator Plus database used in conjunction with Impresario scanners.

evo Front View

evo Top View

evo Rear View

Docking Station Rear View

evo placed in Docking Station

2.2 Indications and Intended Use

The evo Holter recorder is to be used for the non-invasive ambulatory recording of three channel electrocardiograms on an internal, non removable flash memory.

The recorder allows data to be collected over a continuous period of up to 48 hours while allowing the subject to perform most of their normal daily activities.

No analysis is performed by the evo recorder; the recordings can be analyzed on compatible Holter analysis systems from Spacelabs Healthcare

This device has been designed and supplied specifically for the long term recording of electrocardiograms in ambulatory patients using standard Holter monitoring techniques. It shall not be used for any other purposes.

The device shall only be operated by suitably competent personnel trained in the use and procedures of Holter electrocardiography for diagnostic purposes.

2.3 Contraindications

None known.

2.4 Precautions

Follow the cleaning instructions for reasons of basic hygiene and to reduce the risk of cross-infection.

The evo recorder is not intended for use on infants weighing less than 10 Kg.

Under normal operating conditions, the recorder may feel slightly warm upon removal from the docking station.

During patient hook-up, ensure that the electrodes do not come into contact with other metal parts or ground.

2.5 Warning

This device must not be used for direct cardiac application.
Never attempt to connect any other device or instrument to the internal connections or circuitry of the evo recorder while it is connected to a subject.

2.6 Adverse Reactions

Patients may suffer allergic skin reactions from the adhesive of the electrodes, causing reddening, soreness or irritation. Ask the patient if they suffer from these allergies. Contact the electrode provider for further specific information.

2.7 Caution

Federal (USA) law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he practices to use or order the use of the device.

2.8 Conformance to Standards

According to ANSI/AAMI EC38:1998, the evo recorder is a Type 1 ambulatory ECG device.

This device has been designed in accordance with EN60601 -1, “Medical electrical equipment, Part 1: General requirements for safety”, as follows:

1. EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE.
2. EQUIPMENT having a TYPE BF APPLIED PART.
3. ORDINARY EQUIPMENT, without protection against ingress of liquid.
4. Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide, or flammable cleaning agents.
5. Rated for CONTINUOUS OPERATION.
6. EQUIPMENT with an APPLIED PART, specifically designed for application where a CONDUCTIVE CONNECTION is made to the PATIENT, but not directly to the heart.

2.9 Adjustment, Replacement of Parts, Maintenance & Repair

The device requires no routine adjustments to maintain its operation.

The device contains one user serviceable part. It shall be serviced only by Spacelabs Healthcare or by an agent accredited by them to service device of this type. Unauthorized repairs or dismantling of the device will invalidate the warranty.

Only use the docking station mains adapter supplied by Spacelabs Healthcare. Use of the wrong adapter may damage the docking station.

2.10 Defects and Abnormal Stresses

For continued safety the device must not be maltreated, used outside its specified operation conditions, or stored outside its specified storage conditions.

The evo recorder contains protection against electrostatic discharge, but there is no protection against defibrillators. To avoid damage the device should be removed before defibrillating.

Whenever it is likely that protection has been impaired, the device shall be made inoperative and secured against any unintended operation. The protection is likely to be impaired if, for example, the device:

a. shows visible damage

b. fails to perform the intended measurements

c. has been subjected to prolonged storage under unfavorable conditions

d. has been subjected to severe transport stresses

e. the device has been connected to a patient during defibrillation.

2.11 Modifications

For continued safety, the device shall not be subjected to any unauthorized modifications and must be used only for the purpose for which it was originally supplied.

2.12 Declaration of Conformity

CE 0120

This product is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC concerning medical de vices.

2.13 Explanation of Markings

CE 0120	CE MARK
	Year of Manufacture
	Consult Documents THIS SYMBOL MEANS YOU SHOULD READ THE ACCOMPANYING DOCUMENTS
	EQUIPMENT having a TYPE BF APPLIED PART
	If you wish to dispose of this equipment, it must not be disposed of together with ordinary waste but either returned to the manufacturer or to a specialised collection system for used electrical and electronic products
AECG TYPE 1	TYPE 1 AMBULATORY ECG DEVICE ACCORDING TO ANSI/AAMI EC38:1998.
Rx only	Federal (USA) law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he practices to use or order the use of the device.

2.14 Manufacturer

Manufactured for:

Spacelabs Healthcare Limited
1 Harforde Court
John Tate Road
Hertford, Herts.
SG13 7NW
United Kingdom

Tel: + 44 (0) 1992 507700
Fax:+ 44 (0) 1992 501213

Distributed by:

Spacelabs Healthcare Inc.
5150 220th Avenue SE
Issaquah, Washington 98027
United States.

Tel: (425) 657-7200
Fax: (425) 657-7212

Web site: www.spacelabshealthcare.com

This page is intentionally blank.

3. DETAILED OPERATING INSTRUCTIONS

This chapter of the manual provides detailed operating instructions for the evo recorder and the docking station. To help you get started, refer to the separate evo Quick Guides.

You may also need to refer to the Sentinel / CardioNavigator Plus Instruction Manuals.

3.1 First-time Use

The evo is ready to use ‘out the box’ with the Dynamic Energy Source energized for a full 48hour recording.

3.2 Minimum Software Versions

If you are using the Sentinel Data Management software, you must ensure that the software version is V6.0.2.188 or greater.

If you are using the CardioNavigator Plus database, the software version must be V3.05. or greater.

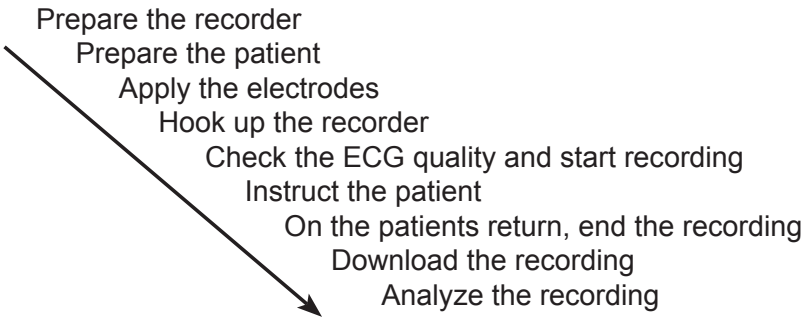
3.3 Manual Recording Identification

If interface with an evo programmer is not available, there is a location for a user label on the back of the recorder. Write the name of the patient on the label and attach the label to the back of the recorder. Note that a suitable pen and a pack of user labels are included with your recorder. A 70% alcohol wipe may be used to erase writing from the label. Please see section 5.8 of this manual for further details.

The recorder stores the date and start time of the recording, together with the serial number of the recorder. If a label is not available, simply note down the recorder serial number (shown on the back of the recorder), date and start time of the recording, together with the patient’s name in a suitable log book.

3.4 Recording Procedure Overview

Step	Description
3.4	Prepare the recorder
3.5	Prepare the patient
3.6	Apply the electrodes
3.7	Hook up the recorder
3.8	Check the ECG quality and start recording
3.9	Instruct the patient
3.10	On the patient's return, end the recording
3.11	Download the recording
3.12	Analyze the recording


Prepare the recorder
Prepare the patient
Apply the electrodes
Hook up the recorder
Check the ECG quality and start recording
Instruct the patient
On the patients return, end the recording
Download the recording
Analyze the recording

3.5 Prepare the Recorder

When the recorder is not in use, the recorder screen will be blank. The recorder is then in 'Sleep mode'.

1. Press the menu navigation button briefly; the recorder will perform a self test.

If a Patient ID is displayed, the recorder has already been configured for a specific patient. *Go to Page 17*.

No Patient ID is shown, there is no patient ID information stored in the recorder. Follow the instructions shown below.

The recorder will indicate the time, date and recording length. This screen indicates that there is no patient ID or ECG data in the recorder.

You may proceed directly to Section 3.6, **Prepare the Patient**, but it is **highly recommended** that you load the patient details (configure the recorder) via the docking station as shown in the next step.

2. Place the recorder in the docking station. (The green LED will light). The configuration procedure depends upon the database that you are using, Sentinel or CardioNavigator Plus. Instructions are given in the relevant user manual.

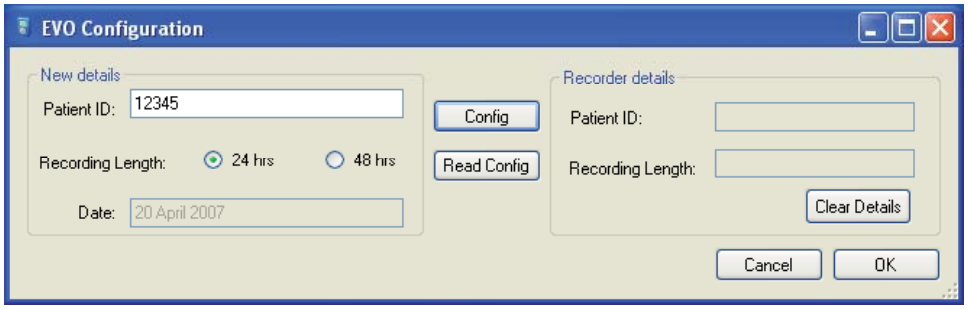
Configuration Procedure for Sentinel Users

Please see the Sentinel User Manual for details.

Configuration Procedure for CNAV+ Systems

1. With the recorder in the docking station, click on the desktop icon.

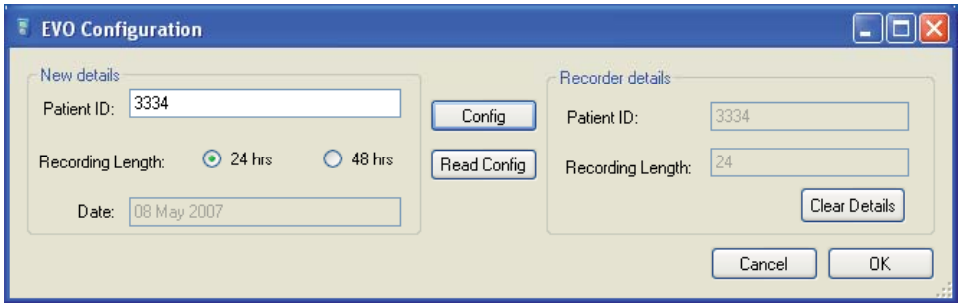
2. The **Evo Configuration** screen will open. Enter in the patient details, select the recording length, then click on **Config**.



Note that if the evo clock is not a the current system time, a message will inform you that the clock in the recorder will be synchronised with the PC.

Once configuration is complete, the Configuration complete message will appear.

The Recorder details will then appear inside the evo configuration screen at the right hand side.



3. Remove the recorder from the dock when the **OK TO REMOVE** message appears on the recorder screen.

Now *go to Section 3.6*, **Prepare the Patient**.

☞ *From page 15*.

The recorder has already been prepared for the next scheduled test. Check that this patient name is correct and press the ►**Confirm** button to continue.

When the recorder is removed from the docking station, the recorder screen is cleared and the amber LED on the docking station will be illuminated.

You should now prepare the patient and hook up the recorder.

Note that you may delete the patient details at this stage if they are not correct by pressing on the ◄**Delete** button. You will be asked to confirm your decision.

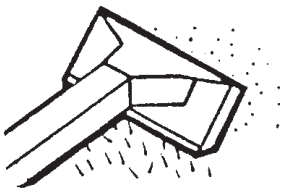
You should then configure the recorder with the correct patient details.

3.6 Prepare the Patient

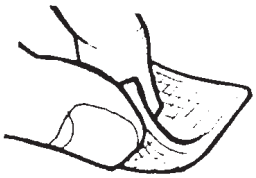
- Proper preparation of the electrode sites and accurate placement of the electrodes are two crucial steps for successful ECG data recording and analysis.
- Success of Holter analysis depends largely on the quality of the recording.
- The recording quality is significantly reduced by artifact, which is caused by improper skin preparation and improper placement of the electrodes.
- Carefully following the steps in this section for preparing all patients will help in obtaining the best recording by reducing artifact.

Prepare the skin

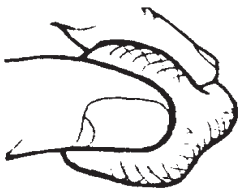
Shave Hair



Clean skin with alcohol wipe*



Gently abrade the skin



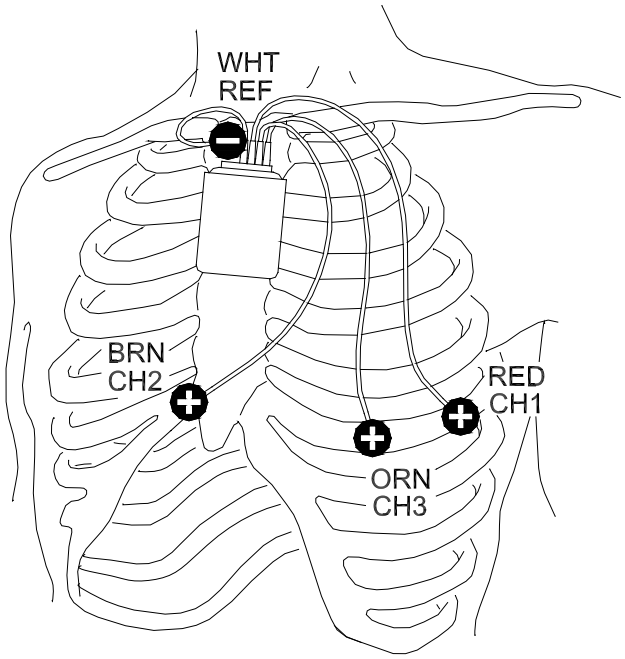
☞. Use good quality electrodes for the final hook-up. We recommend Ambu Blue Sensor types VL-00-S for 24 hour recordings, and VLC-00-S for 48 hour recordings.

* a saline wipe may be used if so wished.

Apply the electrodes

The electrode positions shown on the following pages are suggested but not mandatory. You may find alternative positions more suitable on individual patients.

Standard Hookup



Place all electrodes directly over bone to reduce muscle artifact.

Channel	Color (Polarity)	Location
Common	White (neg.)	Center of manubrium
Ch. 1 Modified CM–V5	Red (pos.)	Left anterior axillary line, 6th rib
Ch. 2 Modified CM–V1	Brown (pos.)	Two centimeters right of the xiphoid process on the rib
Ch. 3 Modified CM–V3	Orange (pos.)	Left mid-clavicular line, 6th rib

3.7 Apply the Electrodes

After you have prepared the electrode sites, remove the electrodes from the package and apply the electrodes as described in the following procedure.

NOTE

Use only silver/silver-chloride electrodes that are suitable for Holter recording.

1. Connect a color-coded, snap-lead wire to an electrode.
2. Remove the adhesive backing of the electrode at the pre-cut separation (located behind the electrode near the gel).

3. Apply the electrode to the prepared site.

4. Smooth the adhesive disk outward, and press it firmly around the edges to ensure good adhesion to the skin.

NOTE

Do not press in the middle of the electrode, because doing so will squeeze out the gel.

3.8 Hook up the Recorder

The evo recorder is either suspended from the patient's neck using a chest-pouch or attached to the patient's belt using the belt mounted pouch option.

Chest-pouch

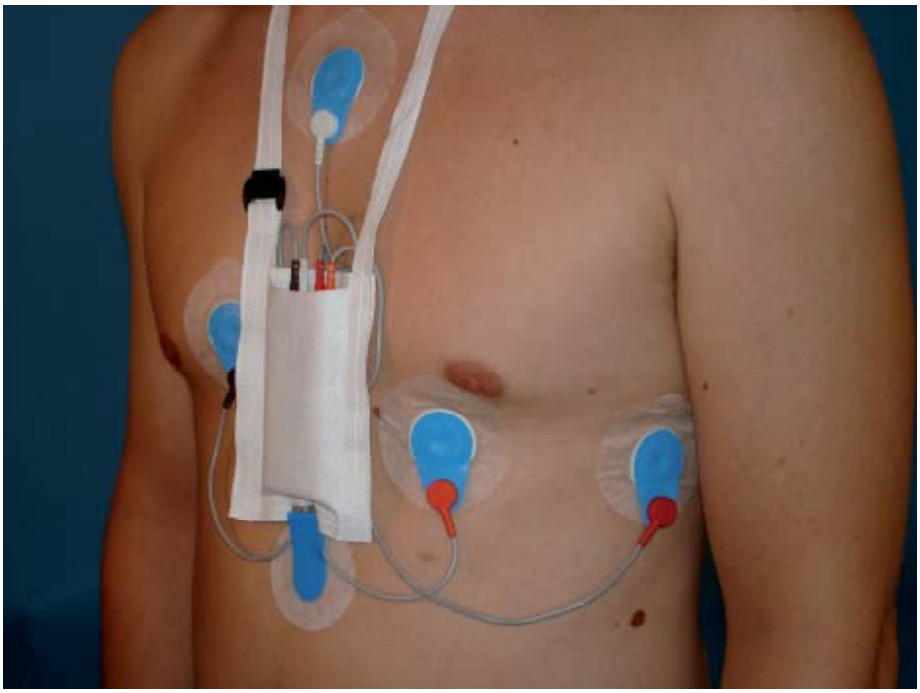
To attach the recorder to the patient using the chest-pouch, perform the following steps:

1. Open the plastic clip on the recorder pouch.

2. Feed the free strap end through the clip.

3. Adjust to the correct length for the patient and press the clip closed. The strap may be cut to the correct length once the clip is fastened.

4. You may fix the lower end of the pouch using a Skin Fix if so wished. (Optional)



Belt-Mount pouch

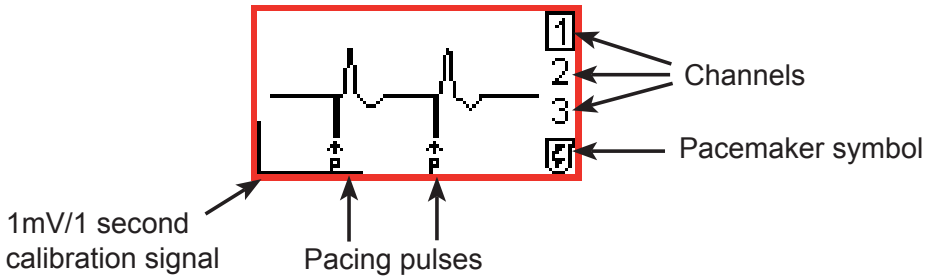
To attach the recorder to the patient using the belt-mounted pouch, perform the following steps:

1. Using the belt clip, attach the pouch to the belt.
2. Insert the recorder into the pouch.
3. Connect the lead wires from the electrodes to the recorder.
4. Secure the wires using a Skin Fix (or equivalent). (Optional)

3.9 Check the ECG Quality

Press the ► **Confirm** button to monitor the ECG.

The current channel being displayed is highlighted on the right of the recorder screen. To review a different channel, press on the▲ Up or ▼ Down arrows on the navigation button.



Note

If left uninterrupted for 10 minutes in the hook-up display, the recorder will start recording automatically.

Check the ECG is of proper amplitude and artifact free. Positional changes and the effects of movement may also be tested.

Press the ► button to move to the next step..

Start the recording by pressing ► '**Yes**' again.

During the recording, the screen shows the time in bold numerals; the semi colon will flash. The screen is not lit.

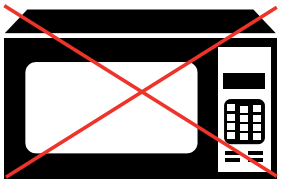
3.10 Instruct the Patient

1. Carry out your normal daily routine.

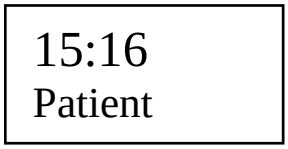
2. Do not pull on the electrodes or leads, or scratch the electrodes.

3. Do not bathe or shower while wearing the recorder.

4. Avoid electric blankets, magnetic fields, industrial machinery.



5. Use the evo clock time to record your activity and symptoms in the diary.



6. If you experience symptoms, press the navigation button on the front of the recorder, and make a note in your patient diary. You may press any of the arrows on the outer rim.

7. To record a diary event, the patient pushes the navigation button briefly. **(If the button is held down for too long, the End Test menu will appear**).

The patient will hear a click. The screen is lit for a few seconds.

3.11 On the Patient's Return

1. When the patient returns, STOP the recording by pressing the navigation button down for 3 seconds. (Any arrow may be used). The patient event screen will appear for 3 seconds.

When the screen is lit use the ◄button to **End the test**. The recording length will be indicated on the screen.

A message will appear asking for confirmation that you wish to end the test. When you confirm **End test**, the display is cleared and the recorder enters sleep mode.

To find out what is available on a recorder, press any arrow on the navigation button. The patient ID and recording details are shown.

If you did not configure the recorder using Sentinel, the recorder screen will show the recorder ID and recording details.

2. Remove the recorder from the chest pouch or the belt pouch.
3. Disconnect the leads from the recorder and the patient.
4. Remove the electrodes and chest pouch (if used) and discard them.
5. Remove the belt and belt mounted pouch (if used) and clean according to the instructions in the maintenance section of this manual.
6. Clean the lead wires according to the instructions in the maintenance section of this manual.
7. Clean the recorder according to the instructions in the maintenance section of this manual.

3.12 Download the Recording

The ECG recording is stored in the recorder's memory and must be transferred (downloaded) to a compatible Spacelabs Healthcare scanning system.

1. Ensure the docking station is connected to the mains power. (*The amber LED is lit when mains power is applied*).

2. Place the recorder in the docking station as shown.(*The green LED will light*).

The recorder screen display will show that download is in progress.

(*The docking station green LED flashes during download*).
Do not remove the recorder during this time.

Remove the recorder from the dock when the **OK TO REMOVE** screen appears.

During the download procedure, the Dynamic Energy Source is topped-up and will be fully re-energized when download is complete. The amber LED flashes during re-energizing.

The re-energize cycle lasts approximately 5 minutes when a 24 hour recording has been made. (10 minutes for a 48 hour recording).

The **OK TO REMOVE** screen will appear when the docking station is inactive and the recorder may be removed from the dock without causing disruption.

It is normal for the recorder to feel slightly warm when it is removed from the docking station after re-energizing.

A message '**COMMUNICATING: DO NOT REMOVE**' will be displayed when transfer of information is taking place between the PC and the recorder. This can be for the transfer of the patient ID, updating the recorder clock or for software updates.

DO NOT remove the recorder from the docking station if this message is displayed; data may be compromised as a result.

3.13 Analyse the Recording

Sentinel Users

Once data has been acquired, the recording may be analyzed using Pathfinder, Lifescreen or Impresario for Sentinel.

CardioNavigator Plus Users

CardioNavigator Plus users should click on the name of the patient in the CardioNavigator Plus database and click the ECG Edit button.

More detailed information is provided in the Sentinel Instruction Manual and the Instruction Manual for each Holter analyzer.

4. MAINTENANCE

4.1 Cleaning and Disinfecting the evo Recorder

The evo Holter recorder has no moving parts and requires no routine maintenance other than cleaning after each use. It has one user replaceable part, the Dynamic Energy Source. Please see section 4.2 for further details.

The plastic parts of the recorder are strong and generally very durable, but some chemicals can attack them. Such chemicals may be found in specialist cleaning products, disinfectants, and skin-care products (e.g. sun blocks).

Due to the enormous range of chemical products, and the fact that some are corrosive in very small quantities, it is often impossible to find out what has caused damage. To ensure trouble-free service from your recorders, use only the cleaners and disinfectants recommended here.

1. Clean the recorder using a soft damp cloth. A mild detergent solution may be used, provided that it is wiped off with a damp cloth and the recorder is dried afterwards. Alternately, you may use an Alcohol Free Cleansing Wipe

2. It can be difficult to remove adhesive residues from the patient cable. We recommend Uni-Patch UP228 swabs, which are also applicable to removing residue from the patient's skin and to cleaning the recorder. Alternately, isopropyl alcohol swabs may be effective but in either case the wipe must be used gently to avoid damaging the cables.

   The patient electrodes are single-use-disposable - do not attempt to clean or reuse them.

3. The belt pouch can be cleaned with isopropyl alcohol or a soft, damp cloth and the belt can be washed in hot soapy water.

Disinfecting the recorder

4. If low-level surface disinfection is necessary, wipe the recorder and cable thoroughly with isopropyl alcohol, 70% (such as isopropyl alcohol prep pads). To avoid damage to the display window, wipe the alcohol off with a soft damp cloth and then dry the window.

4.2 Dynamic Energy Source Replacement Kit

This kit contains detailed instructions for replacement of the Dynamic Energy Source.

NOTE

This procedure may only be performed by a technician who has been trained and accredited by Spacelabs Healthcare.

*Anti-static precautions **MUST** be used while carrying out this procedure.*

*This kit (part No. 050-0517-00) is specific to the evo recorder and may **ONLY** be obtained from Spacelabs Healthcare.*

The Dynamic Energy Source is guaranteed for 3 years.

The evo recorder performs its own self-check before starting a recording. The message on the recorder screen will change from “Battery good” to “Battery OK” as an advance warning to indicate to the user that the Dynamic Energy Source needs to be replaced. *At this stage, there is still sufficient power remaining to perform a 48 hour recording*.

If you suspect that the recorder is not functioning correctly or any assistance is required, contact your supplier or the Service Department at Spacelabs Healthcare.

4.3 evo Recorder Accessories and Consumables

Part Number	Description
50-0034	evo 4 electrode recorder assembly
50-0037	evo Instruction and Technical Manual, English
50-0039	evo hook-up guide
50-0040	evo recorder quick guide (Sentinel), English
50-0200	evo recorder quick guide (CardioNavigator Plus), English
50-0042	evo Belt pouch
41-0686	Waist belt for evo belt pouch
25452-525	4 lead wire set, short with 7" white lead
25452-535	4 lead wire set, short with 14" white lead
25450-187	14" white lead
25452-529	4 lead wire set, long
50-0044	Docking Station with USB connector and EU power cable
50-0045	Docking Station with USB connector and US power cable
50-0169	Docking Station with USB connector and UK power cable
050-0517-00	Dynamic Energy Source Replacement Kit
00-1	evo patient diary, 250 per pack
50-0190	4 Electrode Hook Up Kit For evo Recorder, case of 20 kits
50-0191	4 Electrode Hook Up Kit For evo Recorder With Single Use Pouch, case of 20 kits
50-0050	evo single use pouch, bulk packaged, pack of 50
50-0177	Blank user label

This page is intentionally blank.

5. TECHNICAL MANUAL

5.1 evo Recorder Technical Specifications

ECG Inputs	
Channels	3, type BF applied part patient isolation
Hook-Up	3 channel 4 electrodes, with detachable lead wires
Input impedance	> 10 Mohms
Input DC offset	± 300 mV, with saturation recovery circuit (3 seconds max)
CMRR	> 60 dB at 10Hz, > 80 dB at 50 Hz and above, 2 Vpp signal
Dynamic range	10 mV
Resolution	2.5 µV
Calibration	± 5 %
Bandwidth	0.05 - 40 Hz (-3 dB)
Sampling rate	2048 samples per second per channel
Storage rate	128 Hz
Pacemaker Pulse detection sensitivity	2 mV / 100 µs nominal in any lead
Noise filter	Linear phase filter effective from 50 Hz to > 1MHz,

Data Storage	
Media type	128 Mb non-volatile internal memory
Recording Length	24 or 48 Hours
Data types	full disclosure ECG, with pacing and patient event markers, recording time and date, patient ID

Physical and Environmental Characteristics	
Dimensions	92 x 45 x 15 mm 3.6 x 1.8 x 0.6 “
Weight	70 g / 2.5 oz
User labeling	area provided is 35.2 x 14.7 mm
Operating Power	16 mW typical
Temperature	0 to 45 °C operation, -20 to 65 °C storage
Humidity	operation or storage 5% to 95%, non-condensing
Pressure	operation or storage air pressure 700 - 1060 mbar
Shock	2 m drop

User Interface	
Type	Text menus and keys for up, down, left and right
Languages	US English, German, French, Spanish & Italian
Clock	Clock and calendar (to 2098), 13 mm digit height for patient use.
Ancillary features	Identify unread recordings, warning/error screens for circuit failure and battery
Hook-up display	Real time display of each channel, with 60 µV/30 ms resolution and pacing annotation

Electro-Magnetic Compatibility	
General	Complies with EN 60601-1-2:2001 and ANSI/AAMI EC38:1998
ESD (1)	4 kV air and 2 kV contact discharges: no interruption in recorder function
ESD (2)	8 kV air and 6 kV contact discharges: no damage to the recorder, recording resumes automatically in < 10 s
Radiated emissions	CISPR 11:1997, EN55011:1998 Group 1 Class B
Radiated immunity	3 V/m 26 MHz – 2.5 GHz, 80% AM modulated at 5 Hz. Keyed carrier immunity to EN50082:1996

This equipment has been tested and found to comply with the limits for a class B computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against interference to radio and television reception. This equipment generates and uses radio frequency energy and if not installed and used in accordance with the instructions it may cause interference. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off or on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna
- Relocate the equipment with respect to the receiver
- Move the equipment away from the receiver

If necessary, the user should consult Spacelabs Healthcare or an experienced radio/television technician for additional suggestions. The user may find the following booklet prepared by the Federal Communications Commission helpful:
“How to Identify and Resolve Radio-TV Interference Problems”

This booklet is available from the U.S. Government Printing Office, Washington, DC 20402, Stock No. 004-000-00345-4.

5.2 evo Docking Station Technical Specifications

Docking Station	
PC Interface	Type 2.0 Full Speed 12 Mb/s
Power supply	Spacelabs Healthcare 15W Part numbers 50-0044 (EU) 50-0045 (US) 50-0169 (UK)
Mains supply	100-240 V AC / 50-60 Hz / 400 mA
Data transfer	Optical (infra red) link between recorder and docking station
Firmware	Upgradeable
Standard	EN60950 compliant

The docking station has no user replaceable parts.

Ensure that there is no obstruction to the recorder detection switches.

If there is no message on the display after placing the recorder in the docking station, inspect the switches and remove any dust or debris.

5.3 evo Error Messages

The evo recorder performs a self-test when woken from ‘sleep-mode’ by pressing the menu navigation button.

If the self-test fails, the following screen will appear. Please return the recorder to your supplier if you see this message.

Failed test 01
Failed test 02
Failed test 03
Repeat Test ►

5.4 Software Error Messages and Warnings

Sentinel and CardioNavigator Plus may present error messages when attempting to communicate with evo, for example, if the dock is not powered.

If you are unable to resolve the problem, please note the error number given in the message before contacting Spacelabs Healthcare.

5.5 Firmware Update Utility

evo recorder and evo docking station firmware updates will be available for the user through the evo firmware update CD.

The CD will contain a program to upload firmware updates to the evo recorder or to the evo docking station.

Full instructions for use will be provided with the CD.

5.6 Installation of the Docking Station

1. Connect the dock power supply to the mains and to the dock. When mains power is applied, a green LED will appear on the power supply and the amber LED on the dock will light.

2. Connect the USB cable between the docking station and the PC.

3. The System will recognise that the dock has been connected and will initiate the appropriate driver.

   (First connection only)

Place the recorder in the docking station.

The green LED will flash during data transfer and will turn off when data transfer is complete.

The green and amber LED displays on the dock thus allow the user to distinguish between the following conditions:

Dock Power OK	Amber LED ON
Recorder docked	Green LED ON
Recorder fitted, charger active	Flashing Amber LED
Recorder fitted, data interface active	Flashing Green LED

For more detailed instructions, please consult the information supplied with your docking station.

5.7 Infrared Data Transfer

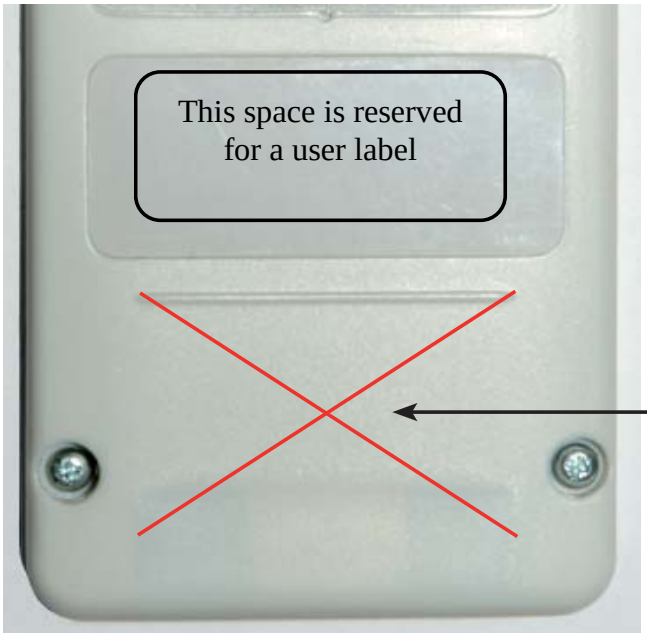
Do not obscure the infra red port on the front of the recorder with a label.

Ensure surfaces are clean and free from dust.

5.8 User Labelling of the Recorder

The back of the recorder has an indented area reserved for a user label, as shown in the diagram below.

Do not place a label lower down on the recorder back – re-energizing the Dynamic Energy Source may be adversely affected.



5.9 User labelling of the docking station

The underside of the docking station also has an indented area reserved for a user label.

6. INDEX

Belt-Mount pouch 21
Caution 10
Chest-pouch 20
Cleaning products 27
Contraindications 10
Defibrillators 11
Disclaimer 5
Docking station 7, 25, 33, 34
Dynamic Energy Source replacement 28
Electrostatic discharge 12
Error Messages 34
Firmware updates 34
Indications and Intended Use 9
LEDs 25, 26, 35
Manufacturer 13
Modifications 12
Navigation button 22
Pacing detection 7
Patient Event button 7
Patient instructions 23
Precautions 10
Quick Guide 15
Self-check 28
Sentinel 7, 15, 17
Skin preparation 18
Skinfix 21
Sleep mode 16
Standard Hookup 19
Standards 11
Technical Specifications 31
Web site 13

This page is intentionally blank.

www.spacelabshealthcare.com

Spacelabs Healthcare inc.
5150 220th Ave. SE
Issaquah
WA 98029, USA

Tel: +1 425 657 7200
Fax: +1 425 657 7212

Spacelabs Healthcare Ltd.
1 Harforde Court
John Tate Road
Hertford, SG13 7NW, UK

Tel: +44 (0) 1992 507700
Fax: +44 (0) 1992 501213

SPACELABS Healthcare

CE 0120